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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,878	11/17/2000	Patrick Rivelli JR.	5877-0011.30	7631

490 7590 05/12/2003

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6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
3731	21

DATE MAILED: 05/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/715,878	RIVELLI, PATRICK
	Examiner (Jackie) Tan-Uyen T. Ho	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 3/4/2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>20</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/4/2003 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 3/4/2003 has been considered and placed in the application file.

Allowable Subject Matter

3. The indicated allowability of claims 1-17 in the Notice of Allowance mailed on 01/13/2003 is withdrawn in view of the reference(s) to Lauterjung (5,707,388) which is cited in the IDS filed on 3/4/2003 and newly discovery reference Lindenberg et al. (6,053,941). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lauterjung (5,630,829).

In regard to claim 1, Lauterjung disclose a stent comprising:

- A plurality of expandable tubular members (figs. 1 and 5), each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks (16, 18) and having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks (16, 18), increases monotonically with an inflection point (20) there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks (col. 5, lines 36-67 and col. 6, lines 18-51);
- Axial connectors (80 or suturing as disclosed in col. 9, lines 22-27) joining one or more confronting peaks of adjacent tubular member;
- Wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one other, without significant change in the axial dimension of the stent.

Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Lauterjung stent which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauterjung (5,630,829) in view of Lindenberg et al. (6,053,941). disclose a stent comprising:

- A plurality of expandable tubular members (figs. 1 and 5), each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks (16, 18) and having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks (16, 18), increases monotonically with an inflection point (20) there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks (col. 5, lines 36-67 and col. 6, lines 18-51);
- Axial connectors (80 or suturing as disclosed in col. 9, lines 22-27) joining one or more confronting peaks of adjacent tubular member;
- Wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one other, without significant change in the axial dimension of the stent.

Although, Lauterjung does not disclose the connectors spaced from one another by intervening, unconnected confronting peaks, attention is directed to the Lindenberg et al. reference which discloses a stent comprising a plurality of expanded tubular member, each member including a plurality of wave segment and each segment having opposite peaks and axial connectors (4, 4a-e) attached to confronting peaks of adjacent members and spaced from one another by intervening, unconnected confronting peaks (figs. 1 and 2, col. 2, line 48 to col. 3, line 29). Lindenberg et al. reference also teaches that in order to attain a great bendability and flexibility of the stent between axially succeeding expanded tubular members are provided in part connected and in part unconnected (col. 1, lines 60-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ connectors as disclosed by Lindenberg et al. into the Lauterjung stent in order to provide a stent with a great bendability and flexibility.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al. (6,053,941) in view of Lauterjung (5,630,829). Lindenberg et al. disclose a stent including :

- A plurality of expandable tubular members (2, 2a, 2b, 2c), each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks (3, 3a, 3b, 3c), wherein the wire element are formed of a NiTi shape memory alloy wherein the shape memory alloy has a stress-induced martensite phase at body temperature

Art Unit: 3731

(inherent) and austenite phase transition temperature below body temperature (col. 3, lines 30-65),

- Axial connectors (4 to 4d) joining one or more confronting peaks of adjacent tubular member, wherein the axial connectors are spaced from one another by intervening, unconnected confronting peaks (figs. 1 and 2, col. 2, line 48 to col. 3, line 29), wherein radial expansion of the stent from its contracted to its expanded state is accommodated by movement of adjacent wave-segment peaks away from one other, without significant change in the axial dimension of the stent.

Although, Lindenberg et al. do not disclose the each segment having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks, attention is directed to the Lauterjung reference which teaches a stent including:

- A plurality of expandable tubular members (figs. 1 and 5), each member being composed of a continuous wire element forming a plurality of wave segments, each segment containing a pair of opposite looped peaks (16, 18) and having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks (16, 18), increases monotonically with an inflection point (20) there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a

Art Unit: 3731

minimum at a point intermediate opposite peaks (col. 5, lines 36-67 and col. 6, lines 18-51),

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the Lindenberg et al. stent having segments, each having a wave shape such that, in the stent's expanded state, the distance between adjacent sides of a wave on proceeding from a peak toward opposite peaks, increases monotonically with an inflection point there between, and in the stent's contracted state, the distance between adjacent sides of a wave is a minimum at a point intermediate opposite peaks. Doing so would provide a stent in its contracted state having circumferential at a minimum in order to be loaded into a small intravascular catheter for delivering and implantation within a small vessel.

9. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al. '941 in view of Lauterjung '388 further in view of Pinchasik et al. (5,449,373). The teaching of Lindenberg et al. in view of Lauterjung (see paragraph 8 above) fails to disclose a stent in its contracted state has inner diameter of between .5 and 2 mm and in its expanded state is between 2-9 times that in its contracted state. Pinchasik et al. reference which disclose a stent for delivering through a curved bodily conduit having constricted and expanded diameters typically fall in the ranges of 1.0-3.5 mm and 3.5-10.0 mm, respectively (col. 3, line 65 to col. 4, line 8). It's also known in the art that human blood vessels typically range from 2mm to 8 mm or may be more or less depending on an individual.

Art Unit: 3731

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stent of Lindenberg et al. in view of Lauterjung having a diameter of between 1-3.5 mm in its contracted state and in its expanded state is between 2-9 times than in its contracted state in order to be easily advanced through vessels having less than 8 mm in diameter as well as to dilate and support the vessels.

10. Claims 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al. '941 in view of Lauterjung '388 further in view of Pinchasik et al. '373 further in view of Ritchart et al. (4,994,069). The teaching of Lindenberg et al. in view of Lauterjung further in view of Pinchasik et al. discloses the stent as claimed (see paragraphs above).

Although, the teaching of Lindenberg et al. in view of Lauterjung further in view of Pinchasik et al. fails to disclose a delivery system and method for delivering the stent into a target vessel having inner diameter less than about 8 mm, attention is directed to the Ritchart et al. reference which disclose treating a method for placing a shape memory implant into a selected vessel by using delivery system designed for accessing small vessel, .05 to 6mm in diameter (col. 3, lines 21-35, col. 6, lines 39-67) wherein the system including a catheter (12) having inner diameter about 40-80% larger than the diameter of the implant (col. 6, lines 39-67), a guide wire for guiding the catheter to the selected vessel and being removed as the catheter reaching the selected site (col. 8, lines 22-38) and the guidewire being replaced with a pusher (16) for pushing the implant out of the catheter (12) into the selected site.

Art Unit: 3731

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Ritchart et al. to employ the delivery system and method designed for accessing small vessel, .05 to 6mm in diameter for delivering the stent of Lindenberg et al. in view of Lauterjung further in view of Pinchasik et al. in order to deliver and deploy the stent to a target site via a tortuous vessel path that has .05 to 6mm or less than 8 mm in diameter.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
May 6, 2003